The Department of Defense Pharmacoeconomic Center

PEC UPDATE

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Focus on the New Statin Contract

Dave Bretzke, RPh, summarizes the provisions of the new statin contract and calculates its economic impact on DoD MTFs- an 18% reduction in the average price per tablet for simvastatin, and an $18 million annual cost avoidance.

The new contract answers cost-effectiveness and clinical concerns by allowing MTFs to add up to two additional statins to their formularies, if they so desire.

- MTFs may add Eon Labs' brand of lovastatin, if desired (but see the caveat about limited availability of the low cost contracted brand).
- MTFs may also add one of the statins not metabolized through the cytochrome P450 3A4 isoenzyme to their formularies, if desired, to meet the needs of patients also receiving other CYP3A4 drugs who are at risk for drug interactions. MTFs may add either fluvastatin or pravastatin, but not both.

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New Drug Watch

Angela Allerman, Pharm.D., rounds up the usual suspects. Also new this month: pharmaceutical trivia! Although this question might not be all that trivial — what common medications are contraindicated in patients with peanut allergy?

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Barb's Barbs

Tastes Great

Dr. Roach discovers a puzzle-making website and pretty much abandons the concept of column-writing.

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PDTS Corner

Update on the Pharmacy Data Transaction Service

Data Integrity Examples - COL (Ret) Roger Williams shares some examples of data integrity issues that impact workload data reports, focussing on problems with quantity dispensed and days supply fields.

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Coming Up

News from the new TRICARE Mail Order Pharmacy (TMOP) program

Some numbers so far...

Number of refill prescriptions transferred from the NMOP upon implementation 1 March 2003: **1.7 Million**

Through 25 April 2003:

Number of prescription requests: **881,138**

Number of prescriptions shipped: **777,129**

Number of calls handled: **339,592**

Excellent Quote of the Month

" My hope is that MTFs will use an evidence-based process to determine to what extent they can use the most cost-effective second-generation antihistamine. Who knows? It might offset some of the increased cost from the PPIs."

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Special Note from the Editors

Yes, you are not imagining it - we had a little lapse in publication -- many apologies! A monthly newsletter can be tricky to do...

But I think we've now found all of the places our authors have been hiding, so we'll forge forward...

ST & JT

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EDITORIAL

The Cost of Choice

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Editors' Letters

Please send your letters to the editors to Dr. Torkildson at **Joseph.Torkildson@amedd.army.mil**

We all like to have choices. Choices allow us to feel like we're in control, and after all, aren't we generally the person most suited to decide what's best for us? In fact, liberty (the right and power to act, believe, or express oneself in a manner of one's own choosing) is defined in our Declaration of Independence as an inalienable right, endowed by our Creator. At this very moment, thousands of our comrades are fighting, and some are dying, to preserve this right for us and hopefully to extend it to others who have not been privileged to enjoy it. Those of us who are physicians took on the added responsibility of making choices for our patients when we took the Hippocratic Oath: "I will follow that system of regimen which, according to **my ability and judgment**, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous." (The emphasis is mine.)

However, although it is a valuable right, the ability to make choices isn't free. There is a cost associated with this privilege. An example of the association between choice and cost is one we are all intimately familiar with, namely the TRICARE program. People who value lower cost over choice gravitate to TRICARE Prime, where a beneficiary's out-of-pocket costs are the lowest. However, their choices regarding who will provide their primary care, which specialist they will see, or whether they will see a specialist at all are fairly restricted. Using the system outside of the established rules results in a substantial financial penalty. People who are willing to pay for a little more choice choose TRICARE Extra. Their list of available providers is still limited to those enrolled in the local network, but their freedom to access these providers is greater. For this privilege, they incur a deductible and co-pay. Patients who are willing to pay for maximum choice opt for TRICARE Standard. These beneficiaries have a true indemnity program, which allows them to seek care from whomever they choose whenever they choose. However, this is reflected in a 5% higher co-pay for provided services, the potential for higher costs if the provider does not accept the TRICARE Maximal Allowable Charge, and the inconvenience of often having to file the paperwork for reimbursement. Once again, there is a direct relationship between level of choice and cost.

As I mentioned earlier, as physicians we make choices for our patients. Among providers, the prevailing opinion is, "the more choices we have, the easier it is for us to use our ability and judgment to benefit our patients". But this is not a classic cost-benefit analysis, for two very important reasons: 1) the benefits we receive from our decision are usually different than those received by our patient, the person for whom the

decision was made, and 2) we don't directly bear the cost of the choice. This creates a situation in which we can choose, either consciously or unconsciously, to base our decisions on benefits and costs other than those that are relevant to our patients. For example, we have a choice between an antibiotic that in clinical trials was effective in treating a particular infection 89% of the time and costs $8.00/course of treatment and one that in different trials was effective 93% of the time and costs $40.00/course of treatment. A civilian patient, faced with the choice of paying five times more out of pocket for the second drug, might decide that this is too much to pay for an additional 4% likelihood of cure, especially if we're talking about a condition like sinusitis or otitis that is not life-threatening. This assumes that the provider actually discusses these options with the patient instead of simply writing for the more expensive product; based on recent anecdotal experience (with my mother-in-law), I have realized that this is usually not the case.

However, in our system, where neither the patient nor the provider are the payor, it becomes easy for the provider to base his or her decision on other issues: the likelihood that the patient will return as a treatment failure, the likelihood of telephone calls resulting from ineffective therapy, etc. The provider may therefore select the more costly drug, given the choice, even though the clinical benefit realized for the patient is too small to justify the significantly greater cost.

Health plans respond to this situation by creating formularies, hoping to save money by decreasing provider choice. There are a number of reasons why this works, related to pricing negotiations in return for formulary status and the relationships between volume sold, profit margin, and net income, but the bottom line is that it works. It works best for the system as a whole when the limitations on choice do not materially affect the provider's ability to benefit patients, but at worst causes them to use a drug that they are not as familiar with as their preferred agent. The challenge becomes to distinguish between the two, as the next example illustrates.

We have been working here for almost a year evaluating the suitability of pursuing a closed class contract for a particular class of drugs. In FY 02, we spent just under $8.2 million on this drug class in the direct care system (MTFs and NMOP). There are three drugs in the class, and the only absolutely clear differences between the drugs are that one has been on the market for seven years while the other two are relative newcomers (both were approved on the same date two years ago), and the older product currently holds a substantial market share advantage within the direct care system. The clinical trial data are not terribly consistent, suggesting that the two newer drugs might have a little better efficacy but might also have a higher incidence of some annoying but not health-injuring side effects. Based on this analysis, we felt we could select one of these drugs for use in patients who required initiation of therapy with a product from this class. Patients already being treated with one of these products would not need to be switched to the winning agent, and we felt the number of patients who would need to be changed to another product, either because therapy with the contracted drug was ineffective or the patient did not tolerate the therapy, would be small. In return, we could expect a reduction in cost of therapy with this class between $2 million and $3.5 million per year.

Now, I will admit we didn't do a very good job of discussing this plan with the providers that would be affected by this contracting action. If I had to do it again, I would do it very differently. On the other hand, leaders of the affected community also were less than successful in providing their providers the opportunity to comment on the proposal. The DoD P&T Committee, which includes a representative from that particular provider community, agreed with our assessment that a contracting action was clinically acceptable. Since then, the pushback from that community has been unexpectedly intense. And one of the more telling comments regarding the implications of this decision came from a provider who stated, "As a practitioner I would like to choose among the three options, or at least 2 of the three available."

As a practitioner, I would also like to have choices when I'm deciding how best to treat my patients. After working here for three years, though, I've also come to greatly appreciate the other side of the coin. Before we

begin picketing against decisions that provide increased cost avoidance by limiting choice, we need to ask ourselves, "What do we base those choices on, and do we really appreciate the cost of being able to choose?"

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DoD P&T Highlights

News from the 5 - 6 March 2003 meetings of the DoD Pharmacy &Therapeutics (P&T) Executive Council and the DoD P&T Committee

Shana Trice, Clinical Pharmacy Specialist
DoD Pharmacoeconomic Center

Time (way past time, really) for another "Cliff Notes" version of the last DoD P&T meeting minutes—for more details, see the complete minutes of the DoD Pharmacy & Therapeutics (P&T) Committee and the DoD P&T Executive Council meetings on the PEC website at www.pec.ha.osd.mil/PT_Committee.htm**.** The next meetings have actually already been held (6 and 7 May at Ft Sam Houston, TX), but the minutes aren't available yet. So let's get caught up...

Quick Links

DoD P&T Executive Council Meeting (5 March 2003)

Drugs / Drug Classes Considered for the Basic Core Formulary (BCF)

- **Added to the BCF:** chlorthalidone; benztropine, trihexyphenidyl, and amantadine; lansoprazole;
  goserelin (Zoladex) 1- and 3-month products (for the treatment of prostate cancer only)
- **Reviewed but not added to the BCF:** metoprolol extended release, ethinyl estradiol/norelgestromin transdermal patches (Ortho-Evra), cholinesterase inhibitors

Contracting / Procurement Issues

- **Contract and BPA awards, renewals, and terminations**
- **Procurement Initiatives:** triptans, oral bisphosphanates, angiotensin receptor blockers, thiazolidinediones, levothyroxine, statins, ophthalmic prostaglandins, insulin pens

DoD P&T Committee Meeting (6 March 2003)

Implementation of the TRICARE Mail Order Pharmacy Program

TMOP Formulary Changes

- **Added to the TMOP Formulary:** adalimumab injection (Humira), aripiprazole tablets (Abilify), atomoxetine capsules (Strattera), eletriptan tablets (Relpax), nitazoxanide 100 mg/5 mL oral suspension (Alinia), teriparitide injection (Forteo)
- **Deleted from the TMOP Formulary:** trovafloxacin (Trovan)
- **Prior Authorization Changes**

DoD P&T Executive Council Meeting (5 March 2003)

Drugs / Drug Classes Considered for the Basic Core Formulary (BCF)

(See Page 4 for a consolidated list of changes to the BCF and the TMOP Formulary)

- **Chlorthalidone added to the BCF** - A MTF provider requested the addition of chlorthalidone, a generic thiazide diuretic, to the BCF in light of the recently completed ALLHAT study, which showed that the thiazide diuretic chlorthalidone was equally efficacious compared to a calcium channel blocker (amlodipine) and an ACE inhibitor (lisinopril) in reducing blood pressure in hypertensive patients, at a much lower cost. Chlorthalidone was also used in the 1991 SHEP trial, which showed a reduced incidence of stroke and major cardiovascular events in elderly patients with isolated systolic hypertension receiving chlorthalidone. The Council decided to add chlorthalidone to the BCF, deciding that the low cost of chlorthalidone and its excellent evidence of benefit supported making the drug uniformly available at MTFs. Hydrochlorothiazide, which is far more commonly used than chlorthalidone, is already on the BCF.

- **Benztropine, trihexyphenidyl, and amantadine added to the BCF as adjunctive therapy agents for Parkinson's disease. Carbidopa/levodopa controlled release considered but not added to the BCF**

  Carbidopa/ levodopa immediate release (Sinemet) is currently the only drug on the BCF for the treatment of Parkinson's disease. The Council addressed the following questions:

  - *Should carbidopa/levodopa controlled release (Sinemet CR) be added to the BCF or replace carbidopa/levodopa immediate release on the BCF?* The Council found no evidence of a clinical advantage for the controlled release formulation relative to the immediate release formulation, and a substantially higher daily cost of therapy, so they did not add carbidopa/levodopa CR to the BCF

Should adjunctive therapy agents (anticholinergic agents and amantadine) be added to the BCF?
Adjunctive therapy agents are effective monotherapy treatment for tremors in patients under the age of 70 in whom akinesia is not a significant problem. Additionally, they may be useful in patients with more advanced disease that have persistent tremor despite treatment with carbidopa/levodopa or dopamine agonists. The Council found little evidence to suggest that one anticholinergic agent is superior to another. Amantadine may have fewer side effects compared to the anticholinergic agents. All three are available as generics and are inexpensive. Since the goal of treatment for Parkinson's is control of symptoms, and no drug gives excellent relief by itself, the Council voted to add these three medications to the BCF.

- *Should one or more of the dopamine agonists (bromocriptine, pergolide, pramipexole, ropinirole) be added to the BCF?* The Council requested the PEC conduct a drug class review to determine which, if any, dopamine agonists, to add to the BCF.

- **Lansoprazole added to the BCF** - The Council accepted blanket purchase agreements offered by Eisai/Janssen for Aciphex and TAP Pharmaceuticals for lansoprazole (Prevacid). Aciphex remains on the BCF; Prevacid was added to the BCF.

- **Goserelin (Zoladex) 1- and 3-month products for the treatment of prostate cancer** - The Council added goserelin acetate (Zoladex) 3.6 mg and 10.8 mg implants to the BCF for the treatment of prostate cancer based on a joint DoD/VA contract for Leutinizing Hormone Releasing Hormone (LHRH) agonists awarded to Astra Zeneca. The contract specifies that Zoladex is the sole LHRH agonist on the Basic Core Formulary (BCF) **for the treatment of prostate cancer**, and that other LHRH agonist dosage forms used for prostate cancer are not allowed on MTF formularies. MTFs are allowed to have additional LHRH agonist products on their formularies for the treatment of conditions other than prostate cancer. Detailed guidance regarding the Zoladex contract is on the PEC website at: www.pec.ha.osd.mil/Contracts/LHRH_Agonist_Contract_Guidance.htm.

- **Metoprolol extended release tablets were reviewed but not added to the BCF -** A MTF provider requested the addition of metoprolol succinate extended release tablets (metoprolol XL) to the BCF for congestive heart failure (CHF), stating that "metoprolol XL is indicated for CHF and is not equivalent to the metoprolol tartrate immediate release preparation (metoprolol IR); additionally the XL formulation provides more dose flexibility by providing low doses to the patient and is the standard of care for CHF patients." After reviewing the efficacy, safety, tolerability, cost, and usage of metoprolol XL and metoprolol IR, the Council voted unanimously not to add metoprolol XL to the BCF, noting that

  - Despite the lack of an FDA-approved indication, DoD providers appear to be using metoprolol IR for CHF. The mortality reduction reported with metoprolol IR appears similar to that reported in other trials of similar design conducted with bisoprolol, carvedilol, and metoprolol XL.
    .
  - Although metoprolol XL offers the convenience of once daily administration and dosing flexibility, a significant advantage in efficacy, safety or tolerability is not evident compared to metoprolol IR. The advantages of metoprolol XL do not justify the higher cost ($9.90-$14.70 /month for metoprolol XL vs, $0.90-$2.42/month for metoprolol IR).

- In the absence of a mechanism for MTFs to target the usage of metoprolol XL to patients with CHF, the addition of metoprolol XL to the BCF would likely result in increased use of metoprolol XL for hypertension in lieu of using other, less-expensive, beta blockers.

- A head to head mortality study of metoprolol IR vs. carvedilol (COMET) is currently underway in Europe, with results expected in summer 2003. The Council plans to reevaluate beta blockers for CHF once results from COMET become available.

- **Ethinyl estradiol/norelgestromin transdermal patches (Ortho-Evra) were reviewed but not added to the BCF -** A MTF provider requested the addition of Ortho Evra to the BCF due to its unique administration route (topical) and potential for increased compliance. After reviewing efficacy, safety, tolerability, cost, and usage, the Council found that while a head-to-head trial comparing Ortho-Evra to an oral contraceptive resulted in a higher mean proportion of patients' cycles demonstrating perfect compliance with Ortho-Evra (88.2% vs, 77.7%, $p<0.0001$), a statistically significant difference in the number of pregnancies was not seen (5 vs. 7, $p=0.57$). In addition, a higher percentage of patients receiving Ortho-Evra discontinued the study due to adverse events. As of Jan 03, about 10,000 prescriptions for Ortho Evra were being filled across the MHS (all 3 pharmacy points of service), compared to approximately 40,000 prescriptions per month for all the oral contraceptives on the BCF combined. The Council concluded that Ortho Evra does not offer any advantages in efficacy or safety/tolerability that justify its higher price compared to oral contraceptives already on the BCF and voted not to add Ortho-Evra to the BCF.

- **Cholinesterase Inhibitors** - Cholinesterase inhibitors are the primary treatment for cognitive symptoms and functional disability of Alzheimer's disease. Four cholinesterase inhibitors are currently available in the United States: tacrine (Cognex), donepezil (Aricept), rivastigmine (Exelon), and galantamine (Reminyl). After discussing the efficacy, safety, tolerability, cost, and usage of this drug class, the Council voted not to consider the addition of a cholinesterase inhibitor to the BCF. The VA plans to conduct a clinical review of the class to determine potential contracting opportunities.

Contracting / Procurement Issues

Contract and Blanket Purchase Agreement Awards, Renewals, and Terminations

- **New joint DoD/VA contracts awarded:** permethrin cream (West-ward), tretinoin topical cream (Allergan), and colchicine tablets (West-ward)
- **Joint DoD/VA contracts not awarded because the bid prices were higher than existing FSS prices:** erythromycin topical and clindamycin topical
- **Joint DoD/VA contracts not awarded for lack of offers:** hydrochlorothiazide/triamterene
- **New Blanket Purchase Agreements (BPAs) signed for:** fluticasone (Flonase; Pharmacia), nisoldipine (Sular; 1st Horizon), tolterodine tartrate extended release capsules (Detrol LA; Pharmacia), lansoprazole (Prevacid; TAP), rabeprazole (Aciphex; Janssen), and levothyroxine (Synthroid; Abbott).

See **DSCP's DMM-Online website** for a **complete list of DoD and DoD/VA**

contracts, including contract prices and NDCs. Questions regarding DoD and joint DoD/VA contracts should be directed to MAJ John Howe at DSCP or LCDR Ted Briski at the PEC.

Procurement Initiatives

- **Joint DoD/VA generic contracts in various stages of solicitation:** isosorbide dinitrate, ketoconazole cream, midazolam injectable, pamidronate injectable, and tramadol tablets

- **Contracts under development:** oral bisphosphonates, angiotensin receptor blockers (ARBs), thiazolidinediones

- **Triptans** - solicitation closed 20 Dec 02, but has been protested to the General Accounting Office (GAO)

- **Levothyroxine -** In light of the recent price increase for the Synthroid brand of levothyroxine (from $0.02 to $0.07 per tablet), the Council considered the possibility of contracting for a specific levothyroxine product for the BCF. Since Synthroid accounts for 97% of MTF usage of levothyroxine, Synthroid has no "A-rated" equivalents, and a contracting action causing switching from Synthroid to another product would result in therapeutic substitutions requiring additional laboratory tests, the Council unanimously voted not to pursue such a contract.

- **Statins** - The new joint DoD/VA high potency statin contract allows (but does not mandate) the addition of generic lovastatin and/or a non-CYP3A4 metabolized statin (pravastatin or fluvastatin) to the BCF. The Council decided the following:

    - **Not to add lovastatin to the BCF**. At present, lovastatin accounts for less than 1% of statin usage at MTFs and (at a cost of $0.26 per tablet for the contracted brand of lovastatin) offers no price advantage compared to simvastatin strengths providing similar reductions in LDL-cholesterol. Individual MTFs may add lovastatin to their local formularies if they determine there is a need to do so.

    - **Not to add a non-CYP3A4 metabolized statin to the BCF** and also to not participate in any contracting initiative that would require addition of pravastatin or fluvastatin to the BCF. Pravastatin and fluvastatin together account for less than 1% of MTF statin usage, at prices higher than those for strengths simvastatin providing similar reductions in LDL-cholesterol. The Council reasoned that since pravastatin and fluvastatin do not offer an economic advantage, their use should be limited to patients who have a clinical need for a non-CYP3A4-metabolized statin. If pravastatin or fluvastatin were added to the BCF, MTFs would no longer be able to use the non-formulary request process to limit usage to patients who have a specific clinical need for these agents. Individual MTFs may add either pravastatin or fluvastatin to their local formularies (but not both) if they determine there is a need to do so.

Contract guidance for the new statin contract is available on the PEC website at: www.pec.ha.osd.mil/Contracts/Statin_Contract_Guidance.htm.
Also see Dave Bretzke's article on Page 6 of this issue of the *PEC Update*.

- **Ophthalmic Prostaglandins -** After a lengthy discussion, the Council reaffirmed its November 2002 decision to seek a contract for a single ophthalmic prostaglandin [latanoprost (Xalatan), bimatoprost (Lumigan), or travoprost (Travatan)]. The Council came to its decision after a review of safety and tolerability data from clinical trials of ophthalmic prostaglandins, data on adverse effects and discontinuation rates from a phase IV study of bimatoprost, VA and DoD usage data, and information about a switch from latanoprost to bimatoprost by a Kaiser health plan.

- **Insulin pens** - The question of whether insulin pens and/or cartridges needed to be added to the BCF arose following the addition of insulin glargine (Lantus) to the BCF in August 2002. It was perceived that increased use of insulin glargine would likely result in increased utilization of these insulin delivery systems, especially for the pre-prandial administration of short-acting and ultra-short-acting insulins. The joint DoD/VA insulin contract awarded to Novo Nordisk in 1999 included only the 10 ml vial package size of human regular, NPH, lente, and NPH/regular 70/30 mix insulin products. Insulin pens and cartridges currently represent a very small fraction of insulin product utilization in MTFs and mail order (about 6% of insulin prescriptions in MTFs and mail order during March 2002 to Feb 2003); however the number of prescriptions for ultra-short-acting insulin preparations (Humalog and Novolog) in pen and cartridge delivery systems grew by about 50% over this period. Prescriptions for other pen and cartridge insulin delivery products remained relatively flat.

  After reviewing the clinical data, the Council agreed that there are data to support the superiority of the ultra-short-acting insulin products (insulin lispro and insulin aspart) compared to regular insulin in terms of glycemic control, HbA1c levels, and frequency of hypoglycemia. There are currently no data that suggest that one ultra-short-acting insulin product is superior to the other. No data have been published since the award of the current insulin contract to suggest that any significant clinical differences exist between the products that were competed at that time, and no additional manufacturers of the products that are currently under contract have been identified. The Council agreed with the following recommendations, to be forwarded for consideration by the Contracting Officer:

- The DoD and VA should not exercise the final option year of insulin contract, which would begin on 1 November 2003.

- The DoD and VA should instead begin development of a solicitation for a new insulin contract that covers different products than the current contract.

    - Lente insulin and the 70/30 product should not be included in the solicitation due to low usage.

    - The ultra-short-acting products (insulin lispro and insulin aspart) should be

included in the solicitation.

- The pen/cartridge delivery system for the ultra-short-acting products only should be included in the solicitation.

DoD P&T Committee Meeting (6 March 2003)

Implementation of the TRICARE Mail Order Pharmacy Program

The new TRICARE Mail Order Pharmacy Program started on 1 March 2003 with a successful transition from the previous National Mail Order Pharmacy (NMOP) program. The URL for the TMOP Formulary page is: www.pec.ha.osd.mil/TMOP/TMOPhome.htm. Comprehensive benefit information for the TMOP may be found on the TRICARE website at: www.tricare.osd.mil/pharmacy/tmop.cfm, while the Express-Scripts website (www.express-scripts.com; click on the DoD seal) provides beneficiaries with the ability to register for the TMOP online, download registration forms, order refills, check order status, etc.

TMOP Formulary Changes – See Appendix A of the Nov 02 DoD P&T Committee minutes for more information.

Added to the TMOP Formulary

- Adalimumab injection (Humira; Abbott) - quantity limit 6 syringes per 6 weeks - requires prior authorization - added to TMOP Covered Injectables List
- Aripiprazole tablets (Abilify; BMS)
- Atomoxetine capsules (Strattera; Lilly)
- Eletriptan tablets (Relpax; Pfizer) - quantity limit 36 tabs/90 days
- Nitazoxanide 100 mg/5 mL oral suspension (Alinia; Romark Labs)
- Teriparitide injection (Forteo; Lilly) - added to TMOP Covered Injectables List

Excluded from the TMOP Formulary

Trovafloxacin was excluded from the NMOP/TMOP since its use is reserved for “patients with serious, life- or limb-threatening infections who receive their initial therapy in an inpatient health care facility,” and is restricted to a two-week period.

TMOP Prior Authorization Changes

The Committee approved prior authorization criteria for the newly approved TNF inhibitor adalimumab (Humira) and modifications to prior authorization criteria for etanercept (Enbrel) and anakinra (Kineret). Prior authorization criteria are now the same for anakinra and adalimumab, providing for coverage for the treatment of moderately to severely active rheumatoid arthritis in patients 18 years of age or older when the patient has had an inadequate response to at least one disease-modifying antirheumatic drug (DMARD). The previous criteria for anakinra required that a patient fail (or be unable to take) methotrexate **AND** fail at least one other DMARD. Prior authorization criteria for both anakinra and adalimumab specify that coverage is **NOT** provided for concomitant use of either of these agents with other TNF inhibitors or anakinra.

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Summary of Changes to the Basic Core Formulary and TRICARE Mail Order Pharmacy Formulary

4

Resulting from the 5-6 March 2003 meetings of the DoD Pharmacy & Therapeutics Executive Council and the DoD Pharmacy & Therapeutics Committee

1. BCF Changes

A. Additions to the BCF

1. Chlorthalidone
2. Benztropine
3. Trihexyphenidyl
4. Amantadine
5. Lansoprazole (Prevacid)
6. Goserelin (Zoladex) 1- and 3-month products for the treatment of prostate cancer only

B. Deletions, changes, clarifications, or exclusions from the BCF - none

2. TMOP Formulary Changes

A. Additions to the TMOP Formulary

1. Nitazoxanide oral suspension (Alinia; Romark Labs)Eletriptan tablets (Relpax; Pfizer) – quantity limits apply
2. Aripiprazole tablets (Abilify; BMS)
3. Teriparitide (rDNA origin) injection (Forteo; Lilly) – added to the TMOP Covered Injectables List
4. Atomoxetine capsules (Strattera; Lilly)
5. Adalimumab injection (Humira; Abbott) – added to the TMOP Covered Injectables List with prior authorization criteria; quantity limits apply

B. Exclusions from the TMOP Formulary

1. Trovafloxacin (Trovan; Pfizer) – specifically excluded from the TMOP Formulary, since its use is reserved for “patients with serious, life- or limb-threatening infections

who receive their initial therapy in an inpatient health care facility," and is restricted to a two-week period.

C. Deletions, Changes, or Clarifications to the TMOP Formulary - none

3. Quantity Limit Changes (TMOP and retail network)

A.

Quantity limit for eletriptan tablets (Relpax; Pfizer): 12 tablets (1 pack) per 30-day supply (retail); 36 tablets (3 packs) per 90-day supply (TMOP); consistent with existing quantity limits for other triptans (within limitations of package size)

B.

Quantity limit for adalimumab injection (Humira; Abbott): 4 syringes (2 packs of 2 syringes) per 4 weeks (retail); 6 syringes (3 packs of 2 syringes) per 6 weeks (TMOP)

4. Changes to the Prior Authorization Program (TMOP and Retail Network) - for details, see Appendix D in the March 2003 DoD P&T Committee minutes

A. Prior authorization criteria established for adalimumab injection (Humira; Abbott)

B. Prior authorization criteria for etanercept (Enbrel) and anakinra (Kineret) modified

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Pharmaceutical Contracting News (a.k.a. Ted's Soapbox)

Second Generation Antihistamines & Blanket Purchase Agreements

LCDR Ted Briski, MSC, USN
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DoD Pharmacoeconomic Center

Just what is going on with the second-generation antihistamines?

As is often the case, history repeats itself, except with a twist

A couple of years ago, DoD had a contract for a single branded proton pump inhibitor (PPI). A me-too product entered the market place and attempted to grow market share by offering a price dramatically lower than any of the other PPIs. DoD was locked into their contract and criticism rained down. Customers quickly forgot the amount of money that had been saved under the contract and longed for the opportunity to further lower their costs by switching to the newer agent. After a few months the contract did expire and MTFs got their wish.

Be careful what you wish for, as the low price didn't last. A significant amount of money was saved over almost a two-year period, but when prices went up there were numerous moans and groans heard throughout the direct care system. Looking at the bigger picture, a total of $114.2 million dollars of PPI expenses have been cost avoided since the beginning of FY 00. So, despite the roller-coaster ride, DoD MTFs have done extremely well with PPIs over the last 31/2 years.

Fast-forward a few months and a similar situation has occurred. DoD has a contract for a single non-sedating antihistamine (NSA). A competitor's product is going both generic and over-the-counter (OTC). Prices are dropping. DoD has an opportunity to be proactive in this case, and decides not to exercise the next option year of their NSA contract so MTFs can gain access to a much less expensive product. Once again, criticism rains down, but by this point in time, we've gotten pretty thick-skinned around here.

Here's the skinny on this one. Currently, the least expensive second-generation antihistamine is less than half the cost of the other two agents. MTFs spend more than $60 Million yearly on second-generation antihistamines. It's simple math, 100% conversion by MTFs to the least expensive product will result in a direct cost avoidance of more than $30 Million. It's obvious there will not, and should not, be 100% use of a single product, but the more use of the least expensive product that occurs, the more money will be available for other products.

Hopefully, it's obvious at this point that the amount of money involved could not be ignored. My hope is that MTFs will use an evidence-based process to determine to what extent they can use the most cost-effective second-generation antihistamine. Who knows? It might offset some of the increased cost from the PPIs. Feel free to contact me at Ted.Briski@amedd.army.mil if you would like to discuss this issue further.

Blanket Purchase Agreements

We spend lots of time working on contracts here at the PEC. The contracting process is a relatively rigid process that involves the clinical assessment of a drug class, formulation of a procurement strategy and collaboration with our VA colleagues to get to a contract that meets both agencies' needs. Contracts always involve a competitive bidding process that can often take months to complete.

A less appreciated strategy is the use of Blanket Purchase Agreements or "BPAs." BPAs are negotiated directly with a manufacturer. A key advantage for BPAs is that they typically can be implemented in much shorter periods of time. A key disadvantage is that since they carry no firm commitment on the part of the government to buy product, they do not yield the same level of discounts typically seen with contracts. However, some situations are better suited for BPAs.

I would like to begin the periodic highlighting of some specific BPAs that I think should be of interest to MTFs. My hope is that by gaining some insights into how and why a BPA came to exist, MTFs will understand the importance of using the preferred BPA products whenever possible.

Last fall it was bought to my attention that MTF orders of azathioprine were routinely being back-ordered. I was able to determine that all the generic manufacturers were experiencing some shortage of raw materials and could not supply product. In an attempt to remedy the situation I approached Prometheus Labs, who is the owner of the branded azathioprine product Imuran. At the time, their price was more than double that of the generic products, but supply was not an issue. In addition, they can provide some value-added assay services to MTFs that have been shown to significantly increase the patient-response rate to azathioprine. I explained to Prometheus that if they could get their price into a competitive range with generics, that MTFs would likely switch to Imuran. The advantages for MTFs include consistent availability, and the use of the branded product at a similar cost to generics.

Prometheus bargained in good faith and offered a BPA price that is substantially lower than their regular FSS price in exchange for the likely increase in sales they would receive. So, now DoD and VA have a BPA with Prometheus labs. Over the last several months the generic shortage of azathioprine has resolved and generic product is now readily available. The result has been that very few MTFs are ordering Imuran. Prometheus may have to discontinue the BPA, and I understand why.

The problem I see from the DoD side of the fence is that generic shortages are common in today's marketplace. Many representative of the generic pharmaceutical industry have relayed that shortages of raw materials can occur at any time. Therefore, it makes sense for DoD to purchase from manufacturers that can assure a steady supply of product, as long as the economic differential is not prohibitive.

I think we all want to buy the least expensive product when we can, but cheapest is not always the most cost effective. We often pay huge price premiums to assure patients have access to the latest pharmacotherapeutic wonders. I think it makes sense to pay a modest price premium to make sure patients have consistent access to tried and true products that don't necessarily get the same marketing and media attention.

BPAs are negotiated to meet the overall needs of the DoD and not necessarily to achieve the lowest price. Although BPAs are not enforceable to the same degree as contracts, they still came into existence for a reason. Therefore, BPA products should be viewed as DoD-preferred whenever possible.

I hope that MTFs will look at their individual azathioprine utilization and consider which product they are purchasing. If sales do not pick up soon, then DoD will lose the Prometheus BPA. That may be ok, if we truly don't need it, but we needed it last fall, and we didn't have it. I would be happy to discuss more of the details if anybody is interested. If you like, send an e-mail message to Ted.Briski@amedd.army.mil.

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Statin Update

Focus on the New Statin Contract

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Clinical Pharmacist
DoD Pharmacoeconomic Center

The new HMG-CoA reductase inhibitor (statin) contract was awarded to Merck for simvastatin (Zocor) last month. The new contract is for 1 year with 4 additional 1 year extensions (for a total of 5 years) and took effect on 1 May 2003. The contract is a joint DoD/VA contact and continues efforts to increase DoD and VA collaboration.

This should cause little disruption to current practice since over 95% of our current MTF statin patients are already receiving simvastatin, the contracted statin under the previous contract. Just keep doing what you are doing now and you'll spend less money on statins. How much less, DoD-wide? Let's find out...

The new prices for simvastatin are as follows:

Strength	Price per tablet
Simvastatin 5 mg	$0.20
Simvastatin 10 mg	$0.26
Simvastatin 20 mg	$0.44
Simvastatin 40 mg	$0.66
Simvastatin 80 mg	$0.89

A complete list of eligible NDCs is found in the Guidance for the New HMG-CoA Reductase Inhibitor (Statin) Contract, available on the PEC website.

The average weighted price per tablet for simvastatin under the old contract was $0.62 (a good deal). With

this new contract, the average weighted price per tablet for simvastatin is $0.51 (a better deal). This represents an **18% decrease and an estimated annual cost avoidance of $16 million dollars**.

What can now be added to MTF Formularies (new contract, new rules)

We have received some confused phone calls concerning the allowance of additional statins on MTF formularies under the new contract. While the guidance document attempted to answer this, here's a more straightforward listing of possible MTF formulary choices.

Basic Rules

- Simvastatin **must** be on all formularies and **must** be used as the initial stain for all patients who have a need for a high potency statin, unless there is a medical necessity to use a different statin.
- Atorvastatin **must not** be on formulary at any MTF.
- MTFs **may** add lovastatin (Eon Labs brand only).
- MTFs **may not** add lovastatin/niacin extended release (Advicor) or lovastatin extended release (Altocor).
- MTFs **may** add **either** fluvastatin or pravastatin, but **not** both.

Statins on MTF Formularies: Possible Scenarios

- Simvastatin only
- Simvastatin and Fluvastatin
- Simvastatin and Pravastatin
- Simvastatin and Lovastatin**
- Simvastatin and Lovastatin** and Fluvastatin
- Simvastatin and Lovastatin** and Pravastatin

**The only lovastatin product allowed on MTF formularies is EON Labs' lovastatin (see guidance). Other lovastatin products, including Merck's Mevacor; KOS's lovastatin/niacin extended release combination product

(Advicor) and Andrx's lovastatin extended release product (Altocor) are not permitted on MTF formularies.

Available at the TMOP

Simvastatin, pravastatin, lovastatin, lovastatin/niacin extended release (Advicor) and lovastatin extended release (Altocor) are available at the TRICARE Mail Order Pharmacy (TMOP) without requiring evidence of medical necessity. Atorvastatin, fluvastatin, and fluvastatin extended release are available from the TMOP only with evidence of medical necessity.

What's the deal with lovastatin?

The addition of generic lovastatin to local formularies should offer a cost-effective alternative to low dose simvastatin if desired. Unfortunately, due to higher than expected usage, the manufacturer of the DoD/VA contracted lovastatin product (Eon Labs) is currently unable to supply enough lovastatin to meet current demand. Since Eon Labs does not expect resolution of the supply problem until at least mid-summer 2003, and lovastatin products from other companies are significantly more costly (most are 5 times the contract price), it's recommended that MTFs verify the availability of Eon Labs' lovastatin prior to adding lovastatin to local formularies.

What's the deal with fluvastatin or pravastatin?

Because simvastatin, lovastatin and atorvastatin are all metabolized by the cytochrome P-450 3A4 isoenzyme (CYP3A4), drugs known to inhibit this pathway can cause drug interactions. Providers may prefer to use fluvastatin or pravastatin for patients who are also receiving chronic therapy with a drug that inhibits CYP3A4. MTFs may add either fluvastatin or pravastatin to their local formulary for patients requiring a non-CYP3A4 statin. However, since the LDL reduction with fluvastatin and pravastatin is significantly lower compared to simvastatin and the cost is nearly double, MTFs should reserve fluvastatin or pravastatin for patients with potential drug interactions, whether it's on formulary or not.

Conclusion

In summary, DoD will continue to provide a safe, well-tolerated statin, with well-proven cardiovascular morbidity and mortality benefits. MTFs should continue to maximize the use of simvastatin to meet the clinical needs of individual patients. If simvastatin will not meet the clinical needs of an individual patient, the MTF pharmacy should provide the most appropriate alternative to manage the patient's clinical needs.

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New Drug Watch

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This month: the first agent for delayed nausea and vomiting following highly emetogenic chemotherapy, an injection for acromegaly, a new AIDS drug, a long-acting beta blocker, the first patch for overactive bladder, and two products in the area of women's health round out this issue's FDA approvals. Also in this issue: the inaugural "Drug Watch Question of the Month" — trivia that might come in handy someday.

Quick Links		
	Newly Approved Drugs from Head to Toe	Product Discontinuations
	New Generics	Safety Updates
	New Indications	New Guidelines

Newly Approved Drugs From Head to Toe

Hematology / Oncology

Aprepitant (Emend; Merck) is a substance P / neurokinin 1 (NK1) receptor antagonist indicated for use in combination with other antiemetic agents for preventing acute and delayed nausea and vomiting associated with highly emetogenic cancer chemotherapy (including high-dose cisplatin; > 50 mg/m2). No other treatments have been approved for treating delayed nausea and vomiting. Aprepitant was administered concomitantly with ondandsetron and dexamethasone in the clinical trials described in the package labeling. Since the drug is a CYP3A4 inducer, drug interactions are a concern.

A 125 mg tablet is given as a loading dose on day one (1-hour prior to chemotherapy), followed by 80 mg QAM on days 2 and 3. A three-tab convenience pack (1x125 mg; 2x80 mg) is available at an FSS cost of ~$190. Aprepitant is also under investigation for the treatment of depression.

Drug Watch Question of the Month

Which medications are contraindicated in patients with peanut allergies?

A. Ipratropium & ipratropium/albuterol metered dose inhalers (Atrovent and Combivent)

B. Ipratropium nebulized solution & nasal spray

C. Progesterone capsules (Prometrium)

D. A and B

Primer on substance P / NK1 receptor antagonists: Substance P is a neuropeptide thought to play a role in the vomiting center located in the brainstem. Neurokinin 1 receptor antagonists can cross the blood brain barrier to counteract the effects of substance P on emetic pathways.

Endocrinology

Pegvisomant (Somavert; Pharmacia) is an injectable treatment for patients with acromegaly who have failed to respond to currently available therapies, such as surgery, radiation therapy, or other medical therapies, or for whom these therapies are not appropriate. There are an estimated 40,000 patients with acromegaly in the US, Europe, and Japan, thus pegvisomant is considered an orphan drug. This product is a growth hormone receptor antagonist, which results in decreased serum concentrations of insulin-like growth factor –1 (IGF-I). Pegviosmant is intended for daily SC self-administration. The vials require reconstitution with sterile water for injection. Monthly monitoring of liver function tests is recommended for the first 6 months of therapy.

Cardiology

A new extended release **propranolol formulation (InnoPran XL; Reliant)** has been approved by the FDA for treating hypertension. This product is labeled for bedtime dosing. Since a New Drug Application (NDA) was submitted by Reliant, InnoPran XL is not considered to be a generic version of Wyeth's Inderal LA. Generic versions of propranolol extended release have been discontinued.

Infectious Disease

Enfuvirtide (Fuzeon; Roche / Trimeris) is a new drug for treating HIV that acts as a fusion inhibitor, blocking the interaction of HIV with CD4+ cells. It is indicated in combination with other antiretroviral agents for treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. Enfuvirtide received accelerated approval from the FDA, and an early release article was published on the New England Journal of Medicine's website (http://nejm.org/earlyrelease/early.asp#3-17) which describes a large clinical trial conducted in over 1000 patients.

Enfuvirtide is intended for SQ self-administration BID and is available in a "convenience kit" containing 60 vials with supplied diluent. Due to a complicated 100-step manufacturing

E. A and C

Answer

E. Ipratropium and ipratropium/albuterol metered dose inhalers (Atrovent and Combivent; Boehringer Ingelheim) use soya lecithin, a legume related to peanuts, as a suspending agent. Anaphylactic reactions have occurred in patients with allergies to peanuts or soybeans who have received Atrovent. Soya lecithin is only used in the Atrovent and Combivent inhalers; the nasal spray and nebulized solution do not contain peanut products. (Source: March 2003 Pharmacists' Letter). The **progesterone capsule** formulation of **Prometrium** (Solvay) contains peanut oil, and is contraindicated in patients with peanut allergies.

Food allergies, in particular peanut allergies, are an increasingly common occurrence in the US, with 1.5 million affected people. (Did anyone notice that airlines have substituted pretzels instead of peanuts for the coach class snack?) [**Editor's note:** IF you get a snack...]

Genentech is studying a monthly injectable anti-IgE monocloncal antibody for peanut allergies, TNX-901, currently in phase II trials (Leung DYM, et al. Effect of anti-IgE therapy in patients with peanut allergy. N Engl J Med; 2003;348:986-93.) Although TNX-901 is on a fast-track status at the FDA, approval is not anticipated for another 3-4 years, as litigation is ongoing between Genentech, Novartis, and Tanox over partnership agreements.

process and limited supply, enfuvirtide will be available on a "first-come, first-served" basis through a sole distributor (Chronimed, Inc). Roche estimates that product will be available for only 12,000-15,000 patients worldwide in 2003, until production is scaled up. Physicians must enroll patients in the limited distribution program via fax. Details on the Fuzeon Progressive Distribution Program may be found at www.fuzeon.com. The anticipated yearly cost of enfuvirtide is $20,000.

Urology

A **transdermal formulation of oxybutynin for treating overactive bladder (Oxytrol; Watson)** has been approved by the FDA. The patch delivers 3.9 mg of oxybutynin daily, and is applied twice weekly. Launch is expected in June 2003.

Women's Health

A new **estradiol acetate vaginal ring (Femring; Galen)** was approved for treatment of moderate to severe vasomotor symptoms associated with menopause as well as symptoms of vulvar and vaginal atrophy. Launch is expected in June 2003. Two dosages will be marketed, 0.05 mg/day and 0.1 mg/day; each ring delivers estradiol over a 3-month period. The findings from the Women's Health Initiative study regarding the risk of stroke, MI, breast cancer, and venous thromboembolism are included in the labeling.

A lower-dose version of **conjugated estrogens / medroxyprogesterone acetate (Prempro; Wyeth)** has been approved. The formulation provides 0.45 mg of estrogen, with 1.5 mg progestin. It is indicated for treating vasomotor symptoms of menopause, and vaginal atrophy. Launch is expected in "early summer 2003."

New Generics

Several generic companies have received FDA approval for **tamoxifen (Nolvadex; AstraZeneca)**. There has been a misconception that Barr has been marketing a generic tamoxifen for about a year. However, Barr has been distributing the AstraZeneca product, using the Barr label, and charging the same price as Nolvadex. Since several generic companies received approval for tamoxifen, the price is expected to decrease.

New generic dosage strengths of **dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate (Adderall)** will soon be available from Barr in 7.5, 12.5 and 15 mg. Previous generics for mixed salts of dextroamphetamine were available in 5,10, 20 and 30 mg.

Azathioprine is now available in 75 and 100 mg tablets from aaiPharma. Previously only a 50 mg tablet was approved.

A suspension formulation of **cefadroxil** has been approved in 125 mg/5 mL 250 mg/5 mL, and 500 mg/5mL strengths from Ranbazy. Launch is expected in June 2003.

New Indications

Carvedilol (Coreg; GSK) is now indicated to reduce the risk of death in clinically stable patients who have had a recent MI and who have LV dysfunction (LV ejection fraction <40%). The expanded indication was based on the results from the Carvedilol Post Infarction Survival Control in Left Ventricular Dysfunction Trial (CAPRICORN; Lancet 2001;357(9266):1385-90), which showed that carvedilol reduced the risk of death by 23%, if administered within 21 days following an MI.

Losartan (Cozaar; Merck) received expanded labeling to reduce the risks of stroke in patients with hypertension and LV hypertrophy. However, there is evidence that this benefit does not extend to African Americans. The Losartan Intervention for Endpoint Reduction in Hypertension study (LIFE; JAMA 2002;288(12):1491-8.) was the basis for approval. The risk of stroke was reduced by 25% with losartan, when compared with atenolol.

The use of rosiglitazone (Avandia; GSK) in combination with insulin has been approved. FDA granted the expanded indication after a 220-patient study found no increase in cardiovascular risk. The previous package labeling had warned against this combination, due to an increased risk of congestive heart failure.

New product labeling for **interferon beta-1b (Betaseron; Schering)** states that it is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations.

Product Discontinuations

Eli Lilly has announced **discontinuation of the manufacture of all IV formulations of cefuroxime (Kefurox), cefazolin (Kefzol) and cefamandole (Mandol)**. Cefazolin and cefuroxime are available from other manufacturers. There is no generic for cefamandole, but other cephalosporins provide the same spectrum of activity.

The **Nitrol brand of nitroglycerin ointment 2% has been discontinued** by Savage Laboratories. Fougera is now the only manufacturer of this formulation.

Safety Updates

Lindane products: New labeling on safety concerns with topical lindane products (shampoos and lotions) have been publicized by the FDA. A patient medication guide is now required when the product is dispensed. The package insert was revised to include a boxed warning describing the risks of using lindane, which stresses that the product is considered a second-line therapy for scabies or lice, due to the potential for neurotoxicity. Lindane should be used with caution in patients weighing <110 pounds. Product package sizes will now be available only in 1 and 2 ounces. The full alert along with other lindane safety information is available at http://www.fda.gov/cder/drug/infopage/lindane/default.htm.

Pergolide (Permax; Lilly/Amarin), used for treating Parkinson's disease, has new warnings describing the incidence of cardiac valvulopathy found during postmarketing surveillance studies. Approximately a dozen patients have developed cardiac valve problems with pergolide, out of nearly 500,000 people. A clear causal relationship has not been determined.

Counterfeit **epoetin alfa (Procrit; Ortho Biotech)** 40,000 units/mL is making the rounds again, following a similar incidence in June 2002. The counterfeit product has been found to have bacterial contamination or no active ingredient. Affected lot numbers and additional information can be found at the Ortho Biotech website: www.procrit.com/counterfeit/letter.html.

New Guidelines

The **Hypertension in African Americans Working Group** has published a consensus document targeted for providers managing this patient population, but the principles can be applied to all patients at high risk for hypertension-related complications. (Management of High Blood Pressure in African Americans. Arch Intern Med; 163:525-41; or www.archinternmed.com - registration may be required). The guideline summarizes pertinent issues of caring for African Americans with hypertension, including their high incidence of stroke and end-stage renal failure. A target blood pressure of <130/80 is recommended for diabetics or patients with proteinuria, which is lower than that suggested in JNC-VI. A comprehensive discussion on the likely need for combination therapy is also included. The American Heart Association Council on High Blood Pressure Research has endorsed the guideline.

New **"Key Clinical Activities for Quality Asthma Care" were released by the Centers for Disease Control and Prevention (CDC)** in Mar 03. Contents of this document were extracted from the two previous documents detailing asthma care released by the National Heart Lung and Blood Institute in 1997 (Expert Panel Report-2; EPR) and 2002 (EPR-Update 2002). The goal is to help health care professionals and administrators define those key areas in providing asthma care the will ultimately reduce morbidity and mortality and burden of illness. Four components are designated essential for providing quality asthma care: assessment and monitoring; control of factors contributing to asthma severity; pharmacotherapy; and education. These 4 components are further broken down in 10 key clinical activities. The document is available on the Morbidity and Mortality Weekly Report (MMWR) portion of the CDC website at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5206a1.htm.

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Barb's Barbs

8

Tastes Great

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Unscramble each of the clue words. Copy the letters in the numbered cells to other cells with the same number.

Tastes Great

What do many OTC weight loss products depend upon for a high ROI (return on investment)?

AGNIMZA

RAGTEEXGDEA

6

RAENYOMT

5

SETPEPNUMSL

TNGISNIHAOS

NIWOKDOH

4

MNMOOSISSI

1

SITANTILMOE

7

RAECMMILCO

3

MAACIGL

ASTIEBUQLONE

2

VEBLEUNALIEB

1 2 3 4 5 6 7

Courtesy of Puzzlemaker

at DiscoverySchool.com

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PDTS Corner

9

Update on the Pharmacy Data Transaction Service

Data Integrity Examples

By COL (Ret) Roger Williams, PDTS CSSC, Clinical Support Supervisor

I was recently asked to provide some specific examples of the data integrity issues we are seeing. In the table below, I've shown some specific examples of two different types of data integrity issues that impact workload data reports: **Quantity Dispensed** and **Days Supply**. Please note the significant impact correcting these transactions had on the total submitted amount due—the corrected total is only about 4% of the originally recorded cost.

The Customer Service Support Center is working with the MTFs to correct these problems — please call if you need help!

#	Drug/Strength/Form	Metric Quantity taken from Transaction	Days Supply taken from Transaction	Package Size	Unit of Measure	Price per Unit of Measure	Calculated Submitted Amount Due	Corrected Submitted Amount Due
1	Cetirizine HCl 1 mg/mL syrup	14,400	30	120 mL	mL	$0.1406	$2,024.64	$16.87
2	Norgestrel / ethinyl estradiol 0.3-0.03mg tablet	2,352	84	28s	tablet	$0.2857	$671.97	$24.00
3	Simvastatin 40 mg tablet	365	30	90s	tablet	$0.8400	$306.60	$306.60
4	Nitroglycerin 0.4 mg/Hr patch TD24	900	30	30s	patch	$0.5227	$470.43	$15.68
5	Cephalexin monohydrate 250 mg/5 mL susp recon	80,000	30	100 mL	mL	$0.0176	$1,408.00	$14.08

6	Acetaminophen 100 mg/mL drops	225	1	15 mL	mL	$0.0967	$21.76	$1.45
7	Metformin HCl 500 mg tablet	120	2	100s	tablet	$0.0410	$4.92	$4.92
8	Clindamycin palmitate 75 mg/5 mL soln recon	40,000	10	100 mL	mL	$0.0836	$3,344.00	$33.44
9	Erythromycin ethylsuccinate 200 mg/5 mL susp recon	40,000	10	200 mL	mL	$0.0314	$1,256.00	$6.28
						Total	**$9,508.31**	**$423.32**

Examples from transactions occurring 5-11 April 2003

Cetirizine syrup - I don't believe the site really dispensed 14,400 mL of cetirizine syrup on this one prescription. This usually occurs because the MTF has the CHCS drug file for this product loaded with the package size of 120 mL. That in itself is not a problem. The problem comes when someone orders a new prescription for this item and enters a quantity of "120" instead of "1." CHCS calculates the metric quantity by multiplying the number entered at the "Quantity Prompt" times the value entered in the "package size" of the ADN file. In addition to giving an erroneous quantity dispensed, the calculated cost of the prescription is significantly increased, as shown in the example.

Norgestrel/EE tablet - This is another example of creating an erroneous quantity and cost of prescription because the wrong quantity was entered. It looks like the site has loaded 28 in the package size for this specific drug and as such, providers should enter quantities of 1, 2, or 3, etc. when they prescribe this oral contraceptive, depending on how many months supply they wish the patient to receive.

Simvastatin tablet - This example illustrates a problem with the **Days Supply** field. While the quantity is high, it is possible the site issued a year supply due to a deployment of special consideration. However, with a drug such as simvastatin, the days supply should not have been 30. I would have expected it to be at least 180 or 365. This impacts the calculation for the Average Days Supply and as such, the number of 30 day equivalent prescriptions dispensed and the average cost per 30 day equivalent prescription. This type of transaction is one example of why I believe the MTF Average Days Supply is understated.

Nitroglycerin patch - Another example of erroneous quantity and cost of prescription resulting from the wrong quantity being entered.

Cephalexin suspension - Another example of erroneous quantity and cost of prescription resulting from the wrong quantity being entered.

Acetaminophen drops - This example actually combines both problems into one. The metric quantity is wrong as well as the days supply. It looks like the site has 15 loaded in the package size for the drops and the provider entered 15 instead on 1. Plus the 1 day supply is wrong. More than likely CHCS could not recognize the directions and therefore a correct days supply could not be calculated. CHCS calculates the Days Supply by comparing the quantity entered with the directions in the Sig. Field. If the directions are something other than the pre-established standard directions, the Days Supply can default to 1, 2 or 3.

Metformin tablet - Another example of an incorrect days supply. While this does not impact the cost of the prescription it does impact the calculation of the Average Days Supply.

Clindamycin solution - Another example of erroneous quantity and cost of prescription resulting from the wrong quantity being entered.

Erythromycin suspension - Another example of erroneous quantity and cost of prescription resulting from the wrong quantity being entered.

The PDTS Customer Service Support Center

The PDTS CSSC strives to provide world-class customer support to all Military Health System users while enhancing the operational effectiveness and ensuring the quality of information maintained within the Pharmacy Data Transaction Service. The PDTS CSSC comprises the Pharmacy Benefit Operations Division of the PEC and is co-located with the Clinical Operations Division of the PEC at Ft. Sam Houston, TX.

The PDTS CSSC has an e-mail address for questions, comments, concerns, or report requests:

PDTS@cen.amedd.army.mil

Drop us an e-mail! We will respond via e-mail or call you within 1 business day.

Or call the PDTS CSSC at:

- DSN: 471-8274
- Toll-free commercial:
  1-866-275-4732
  (1-866-ASK4PEC)
- Local commercial (San Antonio):
  (210) 221-8274
- OCONUS:
  (AT&T access code)+866-275-4732

Need more information?

Many materials pertaining to PDTS, including trouble call procedures, the PDTS Report Request Form, business

rules, and interchange control documents (ICDs), are available in the PDTS section of the PEC website. Just go to **www.pec.ha.osd.mil/pdts/pdts_documents.htm** and browse through the options on the left-hand navigation bar.

In addition, many articles on various aspects of PDTS and the PDTS CSSC have been published in recent issues of the *PEC Update*. Please visit the PEC Update page on the PEC website - **www.pec.ha.osd.mil/ac03000.htm** - for back issues.

We are here to serve you 24 Hours a Day, 7 days a Week.